UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

Office of Chemical Safety
and Pollution Prevention

PC Code: 044309
DP Number: 383634

MEMORANDUM

SUBJECT: **Reclassification of MRID 46907801/46907802 Data Package 336888 for Clothianidin, PC Code 044309 - Revised**

TO: **Kable Davis, Risk Manager Reviewer**
Venus Eagle, Risk Manager, RM 01
Insecticide Branch
Registration Division (7505P)

FROM: **Joseph DeCant, Ecologist** Joseph P DeCant 12/3/10
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

THRU: **Mah Shamim, Branch Chief** MShamim 12/3/10
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

In 2007, the EFED reviewed the study entitled, "An Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, *Apis mellifera* L." (MRID 46907801), and classified it as Acceptable and as satisfying the guideline 850.3040 field study for pollinators. Recently, the EFED has reviewed this study again in light of additional field studies that highlight challenges in field study design and in response to concerns raised by stakeholders. Based on the new review, several deficiencies were identified that lead to the reclassification of this study as Supplemental rather than Acceptable.

In this field study, control and treated plots were each 1 hectare in size and paired, so that 4 sites were established with a control plot paired with a treated plot. These plots were separated by a minimum of 250 m. The study author states, "Of 23 back-up control nectar samples, 2 (field E1C, July 7; field W3C, July 7) had detectable clothianidin residues, at a maximum of 0.922 ppb, suggesting that workers in control colonies may have foraged on clothianidin-treated canola. This may have occurred because the separation between some pairs of control and treated fields was insufficient or because the forage in some control fields was of lower quality…" The inverse may also have occurred. That is, bees placed on treated fields likely foraged on the control fields, which would have reduced the level of exposure to clothianidin residues due to a lack of separation between sites. Bees have been shown to forage up to 6 km

(Visscher and Seeley, 1982) or even twice that in some instances when no competing forage is present (Ratnieks, 2000). The distance of 250 m is inadequate for this separation. The inadequacy is evident given contamination in some of the nectar samples taken from control hives.

Furthermore, the study authors state that, "Approximately 5 g of pollen was analyzed under a light microscope, which confirmed that bees foraged on canola, while the remainder…". This type of identification simply identifies that canola was present in the pollen samples, but does not quantify the proportion of canola pollen present in the sample. This type of pollen evaluation does not characterize the foraging of the bees. The bees in the treated fields could have foraged disproportionately on other uncontaminated sources relative to bees in the control fields. Furthermore, the study authors simply state that to their knowledge, no other forage was present with a radius of 1 km from the edge of the fields. However, given the ability of bees to forage long distances, this lack of data leaves uncertainty in the exposure and suggests that this study did not provide the worst case exposure scenario necessary for use in characterizing risk.

An addendum (MRID 46907802) was submitted later that presented the results of the overwintering part of the study, which revealed that the majority of the hives, including those exposed to clothianidin during the previous season, survived the overwintering period. However, the cross-contamination in the control hives prevents a comparison between the control hives and the treated hives as they relate to whole hive parameters in this addendum. Therefore, this study can only be used to provide a qualitative description of hive survival following the exposure to clothianidin at the levels that were described in the study.

Table 1. Ecological data requirements for clothianidin.

MRID	Guideline	Study Classification[1]	Remarks
469078-01 469078-02 (addendum)	850.3040	Supplemental	This study and associated addendum assessed the toxicity of clothianidin to pollinators using whole hive parameters under field conditions. The study does not satisfy the 850.3040 guideline.

[1]**OPPIN Classifications:**
Acceptable/Guideline; Acceptable/Non-Guideline; Cited; Confirmatory; Decision Deferred; Extraneous submission; In Review; No Decision; Partially Acceptable; Supplemental; Unacceptable/Guideline; Unacceptable/Non-Guideline; Upgradeable.